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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,975	12/27/2001	John Edgar Thomas Corrie	0380-P02671US0	3043

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EXAMINER	
SHAMEEM, GOLAM M	
ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 09/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,975	CORRIE ET AL.	
	Examiner	Art Unit	
	Golam M M Shameem	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-42* is/are pending in the application.

4a) Of the above claim(s) *31-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17 and 18* is/are rejected.

7)☒ Claim(s) *19-30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim of priority under 35 USC § 371 of PCT/GB00/01039 and under 35 USC § 119(a)-(d) to UK 99061932.1 is acknowledged.

Status of Claims

Claims 17-42 are pending in the instant application. Claims 1-16 have been canceled as per the Preliminary amendment filed on 9/18/01. Receipt is acknowledged of amendment / response filed on 7/24/03, and that has been entered. Claims 31-42 are withdrawn from consideration by the Examiner under 37 C.F.R. 1.142 (b) as directed to non-elected subject matter.

Response to Election/Restriction

In response to the restriction requirement, Applicants have elected Group I, claims 17, 20, 22, 24, 26, and 29, drawn to a compound of the formula is acknowledged. During a telephone interview with applicant's attorney Ms. Tong Li, Examiner agrees to rejoin and examine Group II, claims 18, 19, 21, 23, 25, 27, 28 and 30 along with Group I. Applicants also authorize the Examiner to cancel non-elected claims 31-42, when the case is in condition for allowance. Applicants preserve their right to file a divisional on the non-elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17 and 18 are rejected under 35 U.S.C. 112 first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or which it is most nearly connected, to make and/or use the invention without undue experimentation. In claims 17 (New) and 18 (New), the recitation "X is an amino acid, a peptide, oligopeptide or polypeptide" (claim 17, line 6-7, page 3 and claim 18, line 8-9, page 3) broadens the enabling disclosure because the recitation "X is an amino acid, a peptide, oligopeptide or polypeptide" that may encompass a great number of compounds including any amino acids (such as 20 essential amino acids, and an unlimited number of non-essential amino acids) and a wide range of peptide etc. having little or no support in the specification. For rejection under 35 U.S.C. § 112, first paragraph, following factors must be considered in determining whether a disclosure meets the enablement requirement (In *In re Wands*, 8 USPQ2d 1400, 1404 (CAFC, 1988):

1. Nature of invention.
2. State of prior art.
3. Level of ordinary skill in the art.
4. Level of predictability in the art.
5. A mount of direction and guidance provided by the inventor.
6. Existence of working examples.
7. Breadth of the claims,
8. Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The Nature of the Invention

The nature of the invention relates to photo-releasable compounds, to processes for making and purifying these compounds and to their uses.

The State of the Prior Art

The state of the prior art is that there are numerous indoline derivatives that may encompass a great number of compounds. Maryanoff et al (US Pat No. 4,210,590) teach the synthesis of a series of indoline compounds.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* and *in vivo* screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

The predictability or lack thereof in the art

There would be little predictability in the art of which modifications may be made to an indoline derivatives, which would retain its capability as a pharmaceutical grade compound. It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The amount of direction or guidance present

Applicant does not give sufficient direction and guidance in enabling these claims. The quantity of experimentation required to make and use the invention based on the content of the disclosure would therefore be undue because of the level of unpredictability associated with the recitation "X is an amino acid, a peptide, oligopeptide or polypeptide" for an indoline derivatives, their preparation and their use as photo-cleavable precursors. The recitation "X is an amino acid, a peptide, oligopeptide or polypeptide" may encompass a great number of compounds related to indoline derivatives series, however, without some guidance as to what changes may be made to the indoline core formula to obtain a derivative, there would be little predictability in making and/or using such "X is an amino acid, a peptide, oligopeptide or polypeptide". One skilled in the art would not expect any modifications of indoline core compound, which is of pharmaceutical grade.

The presence or absence of working examples

The presence of examples on pages 13-37 for the preparation of indoline derivatives is insufficient for ordinary skill in the art to practice the instantly claimed invention. The specification fails to provide sufficient working examples for what compounds may be made or used which are derivatives of the specifically recited indoline derivatives.

The breadth of the claims

The breadth of the claims is that the indoline derivatives having "X is an amino acid, a peptide, oligopeptide or polypeptide" that may encompass an unlimited number of compounds including any amino acids, peptide, oligopeptide or polypeptide etc.

The quantity of experimentation needed

The quantity of experimentation needed to practice the invention is undue. The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with these claims. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous amount of modifications to perform in order to prepare the indoline derivatives having pharmaceutical grade.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed "X is an amino acid, a peptide, oligopeptide or polypeptide" without undue experimentation; see In re Armbruster 185 USPQ 152 CCPA 1975. Thus, the specification fails to provide sufficient support of the broad use of recitation "X is an amino acid, a peptide, oligopeptide or polypeptide". Genentech Inc. v. Novo Nordisk A/S (CA FC) 42 USPQ2d 1001 , states, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which derivatives can be prepared that encompassed in the instant claims, with no assurance of success. The invention claimed is not described and/or is not enabled in such a way as to satisfy the statutory requirements within the purview of 35 U.S.C. 112 first paragraph. It is suggested that the recitation "X is an amino acid, a peptide, oligopeptide or polypeptide" either be limited to the specific amino acids, peptide actually contemplated in the

specification (for example, rejoining claims 22 and 24 with claim 17) or enable the full range of this recitation to commensurate in scope with these claims.

Objections

Claims 19-30 are objected to as being dependent upon a rejected base claim 17 or 18. The claims should be rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 26-30 are objected to not having a carrier with a composition comprising a compound. It is suggested to incorporate the recitation "a pharmaceutically acceptable excipient, or carrier" (see page 10 of specification) to all composition claims. In claim 17, page 3, line 7, there is an apparent typo in phrase "polypetitide". Appropriate correction is required.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is 703-305-0116. The Examiner can normally be reached on 6:30 am - 5:00 pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 703-308-4537. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7921 for regular communications and 703-308-7921 for after final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

GMShameem

Golam M M Shameem, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1
September 4, 2003